IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ABBVIE INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 4:24-cv-00996-SRC
	)	
ANDREW BAILEY, *in his official capacity as Attorney General of the State of Missouri*, et al.,	)	
	)	
Defendants.	)	

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All Defendants (Missouri Attorney General Andrew Bailey and officers and members of the Missouri Board of Pharmacy) ("State") move the Court to dismiss Plaintiff AbbVie's Complaint, Doc. 1, for failure to state a claim on which relief can be granted and failure to join a necessary party.[1] Fed. R. Civ. P. 12(b)(6), (7). None of AbbVie's claims—takings, preemption, or dormant Commerce Clause—succeed under the facts pleaded in the Complaint. The preemption claim is foreclosed by Eighth Circuit precedent, and the takings and dormant-commerce claims are meritless. This case should be dismissed.

INTRODUCTION AND FACTS

Missouri's S.B. 751 protects freedom of contract for entities that serve disadvantaged patient populations. Many other states have passed laws just like it. But before getting into the substance of S.B. 751, some factual background is helpful to place the law in context.

The federal 340B program is found in 42 U.S.C. § 256b. It sets a price ceiling on outpatient medications, *see id*. § 256b(a)(1), that manufacturers may charge to hospitals and other covered entities who serve a large proportion of low income or otherwise disadvantaged patients. *Id*. § 256b(a)(1), (a)(4) (defining covered entities). "[D]rug manufacturers must 'opt into the 340B program by signing a form Pharmaceutical Pricing Agreement' with the Secretary of [Health and Human Services]." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1141 (8th Cir. 2024), *petition for cert. filed* (July 31, 2024) (No. 24-118) (quoting *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113, 131 (2011)). Drugs subject to a price ceiling are those "purchased by the [covered] entity for which payment is made by the State under the State plan for medical assistance

[1] Plaintiffs are AbbVie Inc., Allergan Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, and Allergan Sales, LLC. Consistent with the Complaint, the State refers to Plaintiffs collectively as "AbbVie."

under title XIX of the Social Security Act [read: Medicaid]." 42 U.S.C. § 256b(a)(3); 42 U.S.C. § 1396 (Medicaid statute – Title XIX of the Social Security Act).

Those covered entities include federally qualified health centers that serve Native Americans, hospitals—including children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, rural referral hospitals, and sole community hospitals—and specialized clinics such as black lung clinics, STD clinics, hemophilia clinics, and tuberculosis clinics.[2] Some covered entities do not have their own in-house pharmacies, so they have to contract with private pharmacies to better serve their patients, many of whom live in rural areas far from the hospital. *McClain*, 95 F.4th at 1139, 1141–42 (noting that "[a]lthough some covered entities have in-house pharmacies, many do not" and that "only about four percent of [covered] entities used in-house pharmacies").

The 340B program also contains restrictions on covered entities and compliance mechanisms for both covered entities and drug manufacturers. *Id.* at 1141. For example, "[c]overed entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug." *Id.* at 1141–42. And "covered entities may not engage in diversion of covered outpatient drugs through 'resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity.'" *Id.* at 1142 (alteration in original) (quoting 42 U.S.C. § 256b(a)(5)(B)). Drug manufacturers like AbbVie dislike the 340B program because the price ceilings cut into their already massive profits.

"When covered entities enter into agreements with contract pharmacies, these pharmacies do not become beneficiaries of the 340B Program. Rather, [the federal Health Resources &

[2] *340B Eligibility*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa/eligibility-and-registration.

Services Administration ("HRSA")] has clarified that 'the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the [340B] program) a process for accessing 340B pricing' for patients." *Id*. at 1142 (citing 61 Fed. Reg. at 43,550). "Covered entities using contract pharmacies . . . still order and pay for the drugs, but they are shipped directly to the pharmacies." *Id*. (omission in original) (quoting *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023)). "Covered entities maintain legal title to the 340B drugs." *Id*. (citing 61 Fed. Reg. at 45,552). Thus, using contract pharmacies "does not in any way extend [340B] pricing to entities which do not meet program eligibility . . . includ[ing] contract pharmacies." *Id*. (quoting 61 Fed. Reg. at 43,550). "Instead, the pharmacy becomes the agent of the covered entity with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant to a prescription.'" *Id*. (quoting 61 Fed. Reg. at 43,550).

The contract-pharmacy distribution model has changed over time with HRSA's guidance. "In 1996, HHS issued guidance saying that covered entities could use one contract pharmacy each." *Sanofi Aventis*, 58 F.4th at 700 (citing 61 Fed. Reg. 43,549). But in 2010 "the use of contract pharmacies skyrocketed" after HRSA "issued new guidance, saying that covered entities could use an unlimited number of contract pharmacies." *Id*. (citing 75 Fed. Reg. 10,272). In response, the "[d]rug makers rebelled" by "adopting policies to limit the use of contract pharmacies." *Id*. AbbVie's policy on contract pharmacies is (1) for covered entities with in-house pharmacies, it will only deliver directly to the in-house pharmacy, and (2) for covered entities without an in-house pharmacy, the entity can designate a single contract pharmacy within 40 miles. Doc. 1 ¶ 75. As AbbVie points out in the Complaint,[3] similar policies have been found consistent

[3] The motion to dismiss assumes the truth of all well-pleaded facts in the Complaint. But the State does not concede that any statements made in the Complaint are well-pleaded facts (as opposed to

with Section 340B by the Third and D.C. Circuits. *See Sanofi Aventis*, 58 F.4th at 704 ("Unless Section 340B 'prohibits' drug makers from adopting their policies, HHS cannot show that they have violated Section 340B. Because Section 340B 'contains no such prohibition,' the drug makers' policies are lawful.) (citation omitted); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir. 2024) ("[W]e hold that section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities."). While restrictive policies like AbbVie's may be lawful, they "cause[] covered entities dependent on contract pharmacies to become unable to serve patients in need." *McClain*, 95 F.4th at 1139.

It is against that backdrop that Missouri, along with a number of other States, sprung into action to protect covered entities and their patients. As of July 11, 2024, Missouri adopted Senate Bill 751, which states (among other things) that drug manufacturers:

> shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by a, covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services. A wholesale drug distributor, as defined in section 338.330, shall not be considered an agent or affiliate [of a drug manufacturer] for purposes of this subsection.

§ 376.414.2, RSMo. S.B. 751 also provides that "[n]othing in this section shall be construed or applied to be in conflict with . . . [a]pplicable federal law and related regulation[.]" § 376.414.6, RSMo. At least seven other states have implemented similar laws that prohibit drug manufacturers from limiting covered entities' freedom of contract.[4]

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legal conclusions) for the purposes of the motion to dismiss. Also, the State does not concede that any statements made in the Complaint are true for the purposes of the rest of this lawsuit.

[4] These include Arkansas (Arkansas Code § 23-92-604), *see McClain*, 95 F.4th 1136; Mississippi (H.B. 728 (2024)), Miss. Code § 75-24-5, *see AbbVie, Inc., et al. v. Fitch*, Civ. No. 1:24-cv-184-HSO-BWR (July 22, 2024); Maryland (HB 1056), *see Novartis Pharmaceuticals Corp. v. Brown et al.*, Case No. 1:24-cv-01557-MJM (D. Md.); Louisiana (Act 358 (2023)), La. Rev. Stat.

AbbVie has sued the Missouri Attorney General and the officials and members of the Missouri Board of Pharmacy, alleging that S.B. 751 is unconstitutional and requesting preliminary and permanent injunctive relief. AbbVie claims that S.B. 751 violates the U.S. Constitution for three reasons: (1) S.B. 751 is an unlawful taking under the U.S. and Missouri Constitutions (Counts I & II); (2) S.B. 751 is field or conflict preempted by the 340B program (Count III); and (3) S.B. 751 violates the dormant Commerce Clause (Count IV). This Court should dismiss this case for failure to state a claim on which relief can be granted because S.B. 751 is not preempted and does not violate the Takings Clauses or dormant Commerce Clause.

ARGUMENT

This Court should dismiss this case for failure to state a claim. To survive a motion to dismiss, a complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *DeCastro v. Hot Springs Neurology Clinic, PA*, 107 F.4th 813, 816 (8th Cir. 2024) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "'[F]actual' matter does not include 'labels . . . or a formulaic recitation of the elements of a cause of action,' 'naked assertion[s] of claims,' or legal conclusions 'couched as' facts." *Id.* (alterations and omissions in original) (quoting *Iqbal*, 556 U.S. 678).

AbbVie has not stated a claim on any of its Counts. Count I fails because S.B. 751 does not "take" any of AbbVie's property. Count II—the state-law takings claim—is barred by the Eleventh Amendment, and it fails on the merits for essentially the same reasons as Count I. Count III should be dismissed because the Eighth Circuit has already ruled that a similar Arkansas statute was not preempted in a suit brought by other drug manufacturers. And Count IV should be

§ 40:2884; West Virginia (S.B. 325), W.V. Code § 60A-8-6a(b)(1); Minnesota (SF No. 5159), Minn. Stat. § 62J.96; and Kansas S.B. 28, Kan. Stat. § 65-483.

dismissed because AbbVie's dormant Commerce Clause theory depends on a glaring misreading of S.B. 751's scope.

I. S.B. 751 does not bring about an unconstitutional taking (Counts I and II).

AbbVie alleges that S.B. 751 violates the Takings Clause of the Fifth Amendment to the U.S. Constitution and Article I, § 28 of the Missouri Constitution. Both claims fail, but because Count II can be quickly disposed of—it is clearly barred by the Eleventh Amendment—the State will address that first.

A. AbbVie's state-law taking claim is barred by the Eleventh Amendment.

The Eleventh Amendment to the U.S. Constitution provides: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." In *Pennhurst State School & Hospital v. Halderman*, the Supreme Court held that "federal courts lack[] jurisdiction to enjoin . . . state institutions and state officials on the basis of [a] state law." 465 U.S. 89, 124–25 (1984). In no uncertain terms, the Supreme Court explained that "it is difficult to think of a greater intrusion on state sovereignty than when a federal court instructs state officials on how to conform their conduct to state law." *Id*. at 106. "Such a result conflicts directly with the principles of federalism that underlie the Eleventh Amendment." *Id*. Eighth Circuit precedent confirms that holding. *See Greene v. Dayton*, 806 F.3d 1146, 1149 (8th Cir. 2015) ("[T]he Eleventh Amendment bars our court from ordering state officials to conform their conduct to state law."); *Randolph v. Rodgers*, 170 F.3d 850, 859 (8th Cir. 1999) ("The Eleventh Amendment precludes a federal court from ordering a state, including its agencies or officials, to conform their conduct to state law."); *Dover Elevator Co. v. Ark. State Univ.*, 64 F.3d 442, 447 (8th Cir. 1995) (state official sued in his or her official capacity is "immune from

suit based on state law claims in federal court"); *O'Connor v. Jones*, 946 F.2d 1395, 1398 (8th Cir. 1991) (holding that it is not "constitutionally permissible for a federal court to conclude that the Missouri Attorney General is violating state law").

In Count II, AbbVie asks the Court to "instruct state officials on how to conform their conduct to state" constitutional "law." *Pennhurst*, 465 U.S. at 106. That is exactly the kind of "intrusion on state sovereignty" that the Eleventh Amendment prohibits. Accordingly, Count II must be dismissed.

B. S.B. 751 does not violate the Fifth Amendment of the U.S. Constitution or Article I, Section 28 of the Missouri Constitution.

The Fifth Amendment to the U.S. Constitution provides: "[N]or shall private property be taken for public use, without just compensation." AbbVie alleges two theories about how S.B. 751 violates the Fifth Amendment. First, AbbVie claims that S.B. 751 is a "private taking" because it "appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies." Doc. 1 ¶ 115. Second, AbbVie alleges that "Missouri effectuates a partial regulatory taking." *Id.* ¶ 116. AbbVie's arguments have already been rejected by one federal district court, and they fare no better here. *See AbbVie Inc. v. Fitch*, 2024 WL 3503965, at *16 (S.D. Miss. July 22, 2024).

1. S.B. 751 is not a per se taking under federal law.

AbbVie's takings claim fails from the outset "because the present case simply does not involve a forced taking of property by the state." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). Contrary to AbbVie's allegations, S.B. 751 does not "compel[] a private transfer of AbbVie's 340-discounted drugs to private, for-profit commercial pharmacies." Doc. 1 ¶ 101. The federal 340B program—not S.B. 751—compels AbbVie to offer its drugs to *covered entities* at discounted rates. And AbbVie joined the

federal 340B program through its own free choice, meaning that the 340B program does not violate the Takings Clause. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) ("a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking").

Neither 340B nor S.B. 751 forces a transfer of ownership from manufacturers to contract pharmacies. The 340B program does not because pharmacies do not "own" the drugs under that program—the covered entities do. The Eighth Circuit has already decided this as a matter of law when it wrote:

> When covered entities enter into agreements with contract pharmacies, these pharmacies do not become beneficiaries of the 340B Program. Rather, HRSA has clarified that "the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing" for patients. 61 Fed. Reg. at 43,550. "Covered entities using contract pharmacies . . . still order and pay for the drugs, but they are shipped directly to the pharmacies." *Sanofi Aventis U.S. LLC*, 58 F.4th at 700. Covered entities maintain legal title to the 340B drugs. 61 Fed. Reg. at 43,552. "The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." *Id*. at 43,550. This includes contract pharmacies. Instead, the pharmacy becomes an agent of the covered entity with the authorization to "dispense 340B drugs to patients of the covered entity pursuant to a prescription." *Id*.

McClain, 95 F.4th 1136, 1142 (8th Cir. 2024) (omission in original); *see also Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024). The Complaint acknowledges that passage from *McClain*, but attempts to distinguish it on the grounds that *McClain* was reviewing an Arkansas law and the same "is not true in Missouri." Doc. 1 ¶ 88. AbbVie cites no authority to support that legal conclusion, and there is none. *McClain*'s statements that that "[c]overed entities maintain title to the 340B drugs," and the "pharmacy becomes an agent of the covered entity" did not depend on some interpretation of Arkansas's law. *McClain* describes the ownership of 340B drugs generally, without regard to whether they are at a contract pharmacy in Arkansas or Missouri.

Neither does S.B. 751 require transfer of title from manufacturers to pharmacies. It only requires manufacturers to permit "acqui[sition]" and "delivery" by the pharmacies. Black's Law Dictionary (12th ed. 2024) (defining "acquire" as "[t]o gain possession or control of"). It says nothing about who must *own* the drugs. Like the Mississippi statute in *Fitch*, S.B. 751 "does not compel Plaintiffs to sell 340B drugs directly to pharmacies," *i.e.*, transfer title to the pharmacies, and "it does not cause takings for private use according to Plaintiffs' theory." 2024 WL 3503965, at *19 (addressing Mississippi House Bill 728).

AbbVie also claims that S.B. 751 violates the Takings Clause by *de facto* forcing a transfer of title between manufacturers and contract pharmacies. AbbVie claims that S.B. 751 does this because many pharmacies *are* actually taking title of the 340B drugs, which AbbVie claims violates 340B. Doc. 1 ¶ 64. But that is not a requirement of S.B. 751. It would be a function of the relationship between covered entities and their contract pharmacies. AbbVie's allegations that some covered entities do transfer title to their contract pharmacies does not turn S.B. 751's contractual-freedom and delivery requirements into a forced private transfer.

Further, S.B. 751's plain terms do not require delivery to a contract pharmacy if DHS prohibits receipt by that contract pharmacy. *See* § 376.414.2, RSMo (prohibiting denial of delivery of drugs to pharmacies authorized to receive them on behalf of the covered entity "*unless* such receipt is prohibited by the United States Department of Health and Human Services" (emphasis added)). If AbbVie thinks that some covered entities and their contract pharmacies are violating 340B and therefore should not be receiving 340B drugs, that is a 340B problem, not a S.B. 751 problem. And this Court cannot determine whether unnamed covered entities are violating 340B in this lawsuit. Not only have these unnamed covered entities not been named as defendants or served with process, but AbbVie also has not exhausted its administrative remedies on that issue.

"[N]o one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *Woodford v. Ngo*, 548 U.S. 81, 88–89 (2006). Whether a covered entity is in compliance with the no-resale and no-transfer provisions of 42 U.S.C. § 256b(a)(5)(B) is governed by administrative dispute resolution. *See* 42 U.S.C. § 256b(d)(3)(A), (d)(3)(B)(i). Thus, to the extent that AbbVie is asking this Court to factually determine whether certain covered entities are violating 340B, that is not a question properly before this Court because AbbVie does not allege that it has brought an administrative action under 42 U.S.C. § 256(d)(3)(A), as required for exhaustion.

This Court also cannot resolve claims about whether particular covered entities are violating 340B because AbbVie has not sued any covered entities it believes to be in violation. This runs afoul of Federal Rule of Civil Procedure 19, which requires parties to be joined "if . . . that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may . . . as a practical matter impair or impede the person's ability to protect the interest." Fed. R. Civ. P. 19(a)(1)(B)(ii). Here, a necessary part of one of AbbVie's Takings Clause claims is that certain covered entities have been violating the 340B program. *See* Doc. 1 ¶¶ 5, 16, 93; *see Two Shields v. Wilkinson*, 790 F.3d 791, 795 (8th Cir. 2015) (claim would require finding that U.S. government acted illegally and breached fiduciary duty). At some point, AbbVie will have to identify these covered entities—likely in discovery. Once it does, AbbVie will be asking this Court to determine whether those covered entities have violated 340B. "The question of whether" the covered entities "ha[ve] acted illegally . . . cannot be tried behind [their] back[s]." *Id*. at 796. Thus, this Court should dismiss for failure to join necessary parties. *Id*. at 797.

This case is similar to *Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, in which the Eighth Circuit rejected a Takings Clause challenge to a Minnesota law that required nursing homes to limit rates for certain residents as a condition for participation in the state's Medicaid program. 742 F.2d at 444. The court held that Minnesota's law "simply does not involve a forced taking of property by the state" because Minnesota nursing homes "have freedom to decide whether to remain in business and thus subject themselves voluntarily to the limits imposed by Minnesota on the return they obtain from investment of their assets in nursing home operation." *Id*. at 446. The court also rejected the argument that "business realities" made participation in the Medicaid program practically involuntary. *Id*. The Eighth Circuit held that "[d]espite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary." *Id*.[5] So too here. AbbVie's voluntary participation in the 340B program precludes its Takings Clause claim.

The Complaint spends much time pointing out what it believes to be policy problems with and abuses of the 340B program. But the existence of alleged flaws with the federal law and alleged abuses by covered entities does not turn S.B. 751 into a taking, much less an unconstitutional one. AbbVie has "made clear [its] frustration with the government's lack of oversight over covered entities' dealings with contract pharmacies, which has forced [it] and other drug manufacturers to absorb the financial impact of … abuses of the 340B system." *Eli Lilly*, 2021 WL 5039566, at *21. But this lawsuit and "the Takings Clause of the Fifth Amendment is

[5] S*ee also Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs*., 2024 WL 3292657, at *12 (D. Conn. July 3, 2024) ("The question, then, is whether the government can use its power as a dominant buyer to demand lower prices from drug manufacturers. The caselaw makes clear that it can."); *Eli Lilly*, 2021 WL 5039566, at *21 ("[W]ithdrawing from the 340B program . . . would result in a significant financial impact for Lilly, but 'economic hardship is not equivalent to legal compulsion for purposes of takings analysis.'") (quoting *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993)).

not the proper vehicle for altering this harsh reality" and "[a]s is so often the case, [AbbVie's] most effective remedy may lie with Congress rather than the courts." *Id*. (quoting *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014)).

2. S.B. 751 is not a per se taking under Missouri law.

Article I, Section 28 of the Missouri Constitution provides "[t]hat private property shall not be taken for private use with or without compensation, unless by consent of the owner…and that when an attempt is made to take private property for use alleged to be public, the question whether the contemplated use be public shall be judicially determined without regard to any legislative declaration that the use is public." AbbVie claims that S.B. 751 violates Article I, Section 28 because it constitutes a "private" taking, i.e., "A-to-B transfers of private property for the benefit of private parties." Doc. 1 ¶ 120. Not so. S.B. 751 does not effect a taking at all. It merely prohibits manufacturers from limiting acquisition and delivery of 340B drugs by contract pharmacies authorized to receive 340B drugs on a covered entity's behalf. *See* Part I.B.1, above. This claim fails for the same reasons the federal takings claim fails.

Even if there were some taking, AbbVie has not pleaded that the taking is for *private use*. "The fact that private parties benefit from a taking does not eliminate the public character of the taking so long as there is some benefit to 'any considerable number' of the public." *Labrayere v. Bohr Farms, LLC*, 458 S.W.3d 319, 328 (Mo. banc 2015) (quoting *State ex rel. Jackson v. Dolan*, 398 S.W.3d 472, 476 (Mo. banc 2013)). S.B. 751 will benefits scores of Missouri citizens who live in rural areas or are otherwise served by covered entities. There is no question that S.B. 751 is "reasonably likely to create some 'public advantage' or 'public benefit.'" *Id*. (quoting *Dolan*, 398 S.W.3d at 476).

3. S.B. 751 is not a regulatory taking under federal law.

AbbVie's argument that S.B. 751 amounts to a regulatory taking fails for many of the same reasons. A regulatory taking occurs when the government "goes too far" in regulating the use of private property. *Cedar Point Nursery*, 594 U.S. 139, 148 (2021). "To determine whether a use restriction effects a taking, [the Supreme] Court has generally applied the flexible test developed in *Penn Central*, balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action." *Id.* (citing *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104 (1978)). Under the *Penn Central* test, S.B. 751 is not a regulatory taking.

First, AbbVie cannot show that S.B. 751 interferes with its reasonable, investment-backed expectations. The Complaint acknowledges that AbbVie "must offer [its] covered outpatient drugs at deeply discounted prices to an enumerated list of 'covered entities'" as "a condition of participating in the federal Medicaid program." Doc. 1 ¶ 2. The 340B program has been around for decades. *Id.* ¶ 33. Since 2010, AbbVie has been on notice that HRSA "would allow covered entities to enter into contractual relationships with an unlimited number of 'contract pharmacies.'" *Id.* ¶ 52 (citing 74 Fed. Reg. 10,272). For years, AbbVie complied with the HRSA's guidance, and it only recently "updated" its policy to restrict the use of contract pharmacies. *Id.* ¶ 75. AbbVie "can hardly argue that its reasonable investment-backed expectations are disturbed" when Missouri passed a law requiring it to distribute 340B drugs "in a manner that was authorized by law" and that AbbVie had already been doing for years. *Ruckelshaus*, 467 U.S. at 1007. As in *Ruckelshaus*, "the force of this factor is so overwhelming" that it is dispositive. 467 U.S. at 1005. "That states might require Section 340B drugs to be distributed for dispensation at private pharmacies should have been foreseeable to Plaintiffs, as Section 340B has had a well-known

'gap' about how delivery must occur since Congress enacted it" and "Congress's silence left delivery options open because 'a matter not covered is not covered.'" *Fitch*, 2024 WL 3503965, at *19 (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012)); *see also McClain*, 95 F.4th at 1143 ("[T]he text of 340B 'is silent about delivery' of drugs to patients.") (quoting *Sanofi Aventis*, 58 F.4th at 703). "In 'an industry,' such as pharmaceuticals, 'that long has been the focus of great public concern and significant government regulation,' enhanced regulation where Congress was previously silent is foreseeable, which cuts against finding a regulatory taking." *Fitch*, 2024 WL 3503965, at *20 (quoting *Ruckelshaus*, 467 U.S. at 1008–09); *see also McClain*, 95 F.4th at 1144 ("Pharmacy has traditionally been regulated at the state level.").

Second, AbbVie fails on the "economic impact" factor. The Complaint does not include any facts about the economic impact of S.B. 751 *on AbbVie* (versus allegations about the economic impact of 340B as a whole, *see* Doc. 1 ¶¶ 42, 54-56, 66-72). Thus, AbbVie has failed to sufficiently allege an economic burden, as required for a regulatory takings claim.

Third, the final *Penn Central* factor (the character of the government action) also favors the State. S.B. 751 ensures that vulnerable patient populations have ready access to the 340B drugs they are entitled to under federal law. Missouri has a strong interest in ensuring affordable healthcare for its citizens, and regulation of the pharmaceutical industry is well within the state's police power.

4. S.B. 751 is not a regulatory taking under Missouri law.

AbbVie's claim that S.B. 751 effects a regulatory taking fails as well. The Missouri Supreme Court has adopted the United States Supreme Court's *Penn Central* test to assess whether a government regulation "'goes too far' in restricting the exercise of property rights." *Labrayere*,

458 S.W.3d at 329 n.6. As explained above, S.B. 751 is not a regulatory taking under federal law. Thus, it is not a regulatory taking under the Missouri Constitution either.

* * *

S.B. 751 does not cause an unconstitutional taking, per se or regulatory, under federal or Missouri law. Accordingly, this Court should dismiss Counts I and II for failure to state a claim. It should also dismiss both Counts I and II for failure to join necessary parties.

II. S.B. 751 is not preempted by federal law (Count III).

Preemption claims stem from Article VI of the U.S. Constitution, which provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." *McClain*, 95 F.4th at 1140 (quoting U.S. Const. art. VI, cl. 2). "Congress may impliedly preempt state law either through field preemption or conflict preemption." *Id*. (quotation marks omitted). The Eighth Circuit has already held that the federal 340B statute does not preempt a similar Arkansas law. That holding controls this case.

A. This Court should dismiss the field preemption claim in Count III.

This Court should dismiss AbbVie's Count III claim that the federal 340B statute field preempts S.B. 751 because the Eighth Circuit has already found that a substantially similar law in Arkansas was not field preempted by the federal 340B statute. *McClain*, 95 F.4th at 1143. The Arkansas law at issue provided that a pharmaceutical manufacturer shall not:

> (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
>
> (2) Deny or prohibit 340B pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Arkansas Code § 23-92-604(c); *McClain*, 95 F.4th at 1142–43. Like S.B. 751, the Arkansas Statute requires drug manufacturers like AbbVie to deliver medications purchased at 340B prices to pharmacies with contracts or arrangements with covered entities. The Eighth Circuit ruled that this kind of law was not preempted by the federal 340B statute. *McClain*, 95 F.4th at 1143.

In holding that the law was not field preempted, the Eighth Circuit addressed three types of field preemption: (1) "[w]hen a federal regulatory scheme occupies the field because of its pervasive nature, leaving no room for state action," (2) "when Congress intends to foreclose any state regulation in the regulated area, irrespective of whether state law is consistent or inconsistent with federal standards," and (3) "a federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id*. (internal quotation marks, brackets, emphasis, and ellipses omitted).

The Eighth Circuit held that the 340B Program is not "so persuasive that Congress left no room for the States to supplement it" because "[p]harmacies have always been an essential part of the 340B program," since the early 1990s when it was first passed, and "[y]et, the text of 340B is silent about delivery of drugs to patients." *Id*. (internal quotation marks omitted). The Eighth Circuit reasoned further reasoned that Congress did not intend to foreclose state regulation in the area of pharmacy delivery and there was not a dominant federal interest in that area because "the practice of pharmacy is an area traditionally left to state regulation," "Congress was aware of the role of pharmacies and state pharmacy law in implementing 340B," and (therefore) "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." *Id*. at 1143–44.

AbbVie claims that the 340B program must field preempt S.B. 751 because 340B is "is a comprehensive federal healthcare program" that "does not authorize state regulation concerning

340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices" and "leaves no room for states to interfere." Doc. 1 ¶ 126. Again, the Eighth Circuit has already rejected that argument. *See McClain*, 95 F.4th at 1143 ("[T]he 340B Program is not 'so pervasive . . . that Congress left no room for the States to supplement it.'") (omission in original) (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)).

AbbVie also alleges that states "may not change the conditions for participation in the federal Medicare and Medicaid programs" and "[a]ny attempt by Missouri to regulate in this area impermissibly changes the requirements for participating in the federal 340B program." Doc. 1 ¶ 127. Not so. S.B. 751 regulates the delivery of 340B drugs, and "the text of 340B 'is silent about delivery' of drugs to patients." *McClain*, 95 F.4th at 1143 (quoting *Sanofi Aventis*, 58 F.4th at 703). "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." *Id.*

Other courts have come to the same conclusion as the Eighth Circuit. For instance, a federal district court in the Southern District of Mississippi held that a similar Mississippi statute was not field preempted by Section 340B. *AbbVie Inc. v. Fitch*, 2024 WL 3503965 (S.D. Miss. July 22, 2024). The Mississippi statute provided:

> (1) A manufacturer or distributor shall not deny, restrict, prohibit or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.
>
> (2) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

Mississippi House Bill 728 (2024) (codified at Miss. Code § 75-24-5).

The court noted that field preemption is not inferred in areas, like pharmacy, that traditionally have been occupied by states unless the "intent to preempt is clear and manifest"—and "not . . . where federal regulations . . . appear to contemplate some concurrent state regulation." *Fitch*, 2024 WL 3503965, at *15. Because pharmacies are an area of traditional state regulation, this triggers the presumption against preemption. *Id.* "[T]here were many gaps in the [340B] legislation" as far back as HRSA's 1996 Guidance, 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996), about dispensation at contract pharmacies, which demonstrates that the statute is not comprehensive enough to create field preemption. *Id.* at *16. The 1996 Guidance addressed whether "contract pharmacy services is inconsistent with section 340B . . . and results in an unauthorized expansion of the program" and concluded that it was not. 61 Fed. Reg. at 43,549. It reasoned: "Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems." *Id.*

This court should join the Eighth Circuit and the Southern District of Mississippi in concluding that statutes like S.B. 751 are not field preempted by the 340B statute and dismiss that aspect of Count III.

B. This Court should dismiss the conflict preemption claim in Count III.

AbbVie's alternative argument that S.B. 751 is conflict preempted fails as well. Once again, *McClain* is dispositive.

The Eighth Circuit ruled that the similar Arkansas law was not conflict preempted because the circumstances did not meet the definition of conflict preemption. *Id.* "[C]onflict pre-emption exists where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of

Congress." *Id*. at 1140 (internal quotation marks omitted). "What qualifies as a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id*. at 1144 (internal quotation marks omitted). "If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power." *Id*.

The Eighth Circuit held that a law like Missouri's S.B. 751 did "not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite" because it "fulfill[s] the purpose of 340B." *Id*. That purpose is ensuring that covered-entity patients can conveniently access 340B drugs. *See id*. at 1144–45. So too here. Before Missouri passed this law, AbbVie had changed its policy to allowing each covered-entity hospital to only use ***one*** contract pharmacy (or zero, if the covered entity had a pharmacy in-house). Doc. 1 ¶ 75. In rural areas, this greatly decreases the value of the 340B program to covered entities, whose patients may live long distances away from the covered entity and the one pharmacy it picked to receive 340B medications.

Like the Arkansas Statute upheld by the Eighth Circuit, S.B. 751 "does not require manufacturers to provide 340B pricing discounts to contract pharmacies" or "set or enforce discount pricing." *McClain*, 95 F.4th at 1145. "As such, the delivery of a covered entity's 340B's drugs to contract pharmacies for dispensing creates no obstacle." *Id*. Like the Arkansas statute, S.B. 751's "penalties are aimed at activity that falls outside the purview of 340B"—namely "interfering with a covered entity's contract pharmacy arrangements." *Id*. Therefore, because there is no obstacle for pharmaceutical manufacturers to comply with both S.B. 751 and Section 340B, there is no conflict preemption.

The Complaint alleges that S.B. 751's enforcement scheme conflicts with 340B's. AbbVie argues that "Congress tasked neither the Attorney General of Missouri nor the Missouri Board of Pharmacy with enforcement of the 340B statute" and "[s]tate enforcement 'would undermine the agency's efforts to administer these two programs harmoniously and uniformly." Doc. 1 ¶ 129 (quoting *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011)). That argument fails because the enforcement schemes are about two very different things. HHS's administration and enforcement power covers only those things addressed in the 340B statute—namely pricing. *See McClain*, 95 F.4th at 1141–42 (noting that the 340B program "requires manufacturers to sell drugs to covered entities at a discounted 'ceiling price,'" which "is determined by statutory formula"). The 340B enforcement mechanism is in 42 U.S.C. § 256b(d)(3), which creates an ADR process

> for . . . claims by covered entities that they have been overcharged for [340B] drugs . . . , and claims by manufacturers, after the conduct of audits [of covered entities by manufacturers or the Secretary], or violations of subsections (a)(5)(A) [prohibiting covered entities from requesting Medicaid reimbursement for discounted 340B drugs] or (a)(5)(B) [prohibiting resale of discounted 340B drugs to nonpatients.]

The Eighth Circuit reasoned that the 340B Program "includes compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process," but it "is silent about delivery and distribution of pharmaceuticals to patients." *McClain*, 95 F.4th at 1140 (internal quotation marks omitted). Allowing the Missouri Board of Pharmacy to investigate violations of S.B. 751, which is about delivery, does not conflict with the 340B's enforcement scheme relating to pricing. § 376.414.2 ("A pharmaceutical manufacturer . . . shall not deny, restrict, or prohibit . . . the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity . . . ."). AbbVie alleges in a conclusory fashion that "S.B. 751's attempts to install an alternative compliance regime conflict with the procedures detailed in the 340B statute and the lawfully

promulgated federal rules implementing the statute." But AbbVie fails to allege facts that show any actual conflict. The fact that 340B and S.B. 751 have different enforcement mechanisms to address different problems is not a basis for conflict preemption.

In *Fitch*, the U.S. District Court for the Southern District of Mississippi also agreed with the Eighth Circuit about conflict preemption. *See* 2024 WL 3503965, *11-13. First, the court reasoned that the bill plainly fell under the umbrella of a health and safety regulation, meaning that it triggered the presumption against preemption. *Id*. at *19. Next, it noted that "Section 340B does not explicitly mandate how delivery of discounted drugs is to occur." *Id*. at *22. Finally, it stated that conflict preemption was unlikely because Mississippi's statute "arguably *promotes* Section 340B's objective by ensuring covered-entity patients can conveniently access 340B drugs." *Id*. at *23 (emphasis added).

AbbVie's Complaint also argues that "Missouri also has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies." Doc. 1 ¶ 131. That is not what Missouri's law does. Missouri's law prohibits drug manufacturers from denying, restricting, or prohibiting acquisition or delivery of 340B drugs to contract pharmacies that are acting as agents of covered entities. Contrary to AbbVie's contention,[6] nothing in S.B. 751 forces transfer of title to contract pharmacies, and the pharmacies are required to be acting on behalf of the covered entities. Thus, AbbVie can comply with both 340B and S.B. 751 at the same time, and S.B. 751 is not inconsistent with the federal 340B law's purpose of subsidizing covered entities. In fact, instead, it supports the goal of subsidizing covered entities against manufacturers that have become increasingly and more creatively stingy.

[6] *See* Doc. 1 ¶ 88.

III. S.B. 751 does not violate the "dormant" Commerce Clause (Count IV).

AbbVie's dormant Commerce Clause challenge "begin[s] in a tough spot." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 370 (2023). AbbVie does not allege that S.B. 751 "seeks to advantage in-state firms or disadvantage out-of-state rivals." *Id.* Nothing in the Complaint suggests that S.B. 751 offends the "antidiscrimination principle" that "lies at the "very core" of [the Supreme Court's] dormant Commerce Clause jurisprudence." *Id.* at 369 (quoting *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 581 (1997)). Instead, AbbVie alleges that "S.B. 751 runs afoul of the Constitution's Dormant Commerce Clause because it purports to 'directly regulate out-of-state transactions by those with no connection to the state.'" Doc. 1 ¶ 133 (quoting *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356,376 n.l (2023)). The Complaint mischaracterizes the dormant commerce clause jurisprudence and S.B. 751's effects.

A. S.B. 751 does not violate the dormant Commerce Clause based on unlawful extraterritoriality.

AbbVie alleges that S.B. 751 is Missouri's attempt to regulate "virtually every manufacturer, covered entity, and pharmacy in the country." Doc. 1 ¶ 138. According to AbbVie, S.B. 751 controls "a transaction between a drug manufacturer located in Illinois, its wholesaler in Kentucky, and a California contract pharmacy that dispenses the drug to a Texas resident." *Id.* Not so. Those allegations are legal conclusion, not well-pleaded facts. They are also *incorrect* legal conclusions that fall apart as soon as one considers Missouri's law on extraterritoriality and the Supreme Court's dormant Commerce Clause jurisprudence.

A statute presumptively has no extraterritorial application. *Kiobel v. Royal Dutch Petroleum Co.*, 569 U.S. 108, 115 (2013). This canon of construction applies equally "to the laws of our states." Scalia & Garner, *Reading Law* at 268 (2012 ed.). And it applies to Missouri statutes like S.B. 751 "absent express text to the contrary." *See Tuttle v. Dobbs Tire & Auto Ctrs., Inc.*,

590 S.W.3d 307, 311 (Mo. banc 2019). Here, S.B. 751 does not expressly state that it applies outside "the boundaries of this state," meaning that it "ha[s] no extraterritorial effect." *Id*. Thus, AbbVie has failed to state a claim on the basis that S.B. 751 regulates out-of-state conduct.

While AbbVie cites to *National Pork Producers*, that case does not support its theory. S.B. 751 does not purport to directly regulate transactions which occur wholly outside of Missouri and involve individuals having no connection with Missouri. If AbbVie is outside of Missouri and contracting outside of Missouri, S.B. 751 might affect it if AbbVie's contracts with a third party purposely limit that third party from delivering AbbVie's 340B drugs to certain Missouri contract pharmacies that have contracts with a covered entity. But that does not violate the dormant Commerce Clause because AbbVie's goal would be to impact entities inside Missouri.

AbbVie also cannot state a claim on the basis that S.B. 751 has the *practical effect* of controlling commerce outside of a state. A majority in *National Pork Producers* agreed that there is no *per se* rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside of a state. 598 U.S. at 373–75. Such an interpretation would lead to "strange places," as "many (maybe most) state laws have the practical effect of controlling extraterritorial behavior." *Id*. at 374 (internal quotation marks omitted). For instance "[s]tate income tax laws lead some individuals and companies to relocate to other jurisdictions," and "[e]nvironmental laws often prove decisive when businesses choose where to manufacture their goods," not to mention "the extraterritorial-effects [of] all manner of libel laws, securities requirements, charitable registration requirements, franchise laws, tort laws," "inspection laws, quarantine laws, and health laws of every description" that have a "considerable influence on commerce" outside their borders." *Id*. at 374–75 (internal quotation marks omitted, brackets accepted). Thus, the rule AbbVie wants this Court to accept was directly addressed and rejected by a majority in *National*

Pork Producers because such a rule "would cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers." *Id*. at 375.

The Supreme Court stated that the cases cited for impermissible extraterritorial effect were, in reality, only discrimination cases. *Id*. at 374. Because there is no discrimination here, there is no dormant commerce clause violation via this theory. S.B. 751 is not one of the kinds of law identified by the Supreme Court as violating the dormant Commerce Clause for "extraterritorial effect," as it is not a tariff, does not require sales at a particular price, and it is not a price-control or price-affirmation statute that ties the price of in-state products to out-of-state prices. *See National Pork Producers*, 598 U.S. at 372.

To the extent that there is some question about the scope of the law, and to the extent that affects the constitutionality of S.B. 751, this Court should not "construe[ ]" it "to be in conflict with . . . [a]pplicable federal law," including the dormant Commerce Clause. § 376.414.6, .6(1), RSMo.; *see also NFIB v. Sebelius*, 567 U.S. 519, 562 (2012) (applying the canon of constitutional avoidance, which commands that "as between two possible interpretations of a statute, by one of which it would be unconstitutional and by the other valid, [a court's] plain duty is to adopt that which will save the Act"). S.B. 751 does not violate the dormant Commerce Clause under the "unlawfully extraterritorial" theory.

B. The Complaint does not allege that S.B. 751 violates the dormant Commerce Clause by a discriminatory intent or effect or by creating a substantial burden on interstate commerce.

Extraterritoriality is the only basis for AbbVie's dormant Commerce Clause claim that is alleged in the Complaint. The Complaint does not allege that S.B. 751 is unconstitutional because it "implicate[s] the antidiscrimination principle at the core of this [the Supreme Court's] dormant Commerce Clause cases." *Nat'l Pork Producers*, 598 U.S. at 371. No form of the word "discriminate" even appears in the Complaint. Nor does Count IV plausibly allege that S.B. 751

substantially burdens interstate commerce. To the extent AbbVie responds that S.B. 751 is discriminatory and substantially burdensome, those arguments should be rejected. "[I]t is axiomatic that a complaint may not be amended by the briefs in opposition to a motion to dismiss." *Al-Saadoon v. Barr*, 973 F.3d 794, 805 (8th Cir. 2020) (alteration in original) (quoting *Morgan Distrib. Co. v. Unidynamic Corp.*, 868 F.2d 992, 995 (8th Cir. 1989)). S.B. 751 does not violate the dormant Commerce Clause.

CONCLUSION

For these reasons, this Court should dismiss this case for failure to state a claim.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2024, the foregoing was filed electronically through the Court's electronic filing system to be served electronically on counsel for all parties.

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